IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IDENIX PHARMACEUTICALS LLC and UNIVERSITA DEGLI STUDI DI CAGLIARI, Plaintiffs, v. GILEAD SCIENCES, INC., Defendant.	C.A. No. 14-846-LPS

GILEAD'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR JMOL, NEW TRIAL, REMITTITUR, AND SEVERANCE/STAY OF ONGOING ROYALTY PROCEEDINGS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

ARGUMENT

I. Idenix's *Wyeth* Arguments Contradict Express Federal Circuit Precedent

An iterative process of synthesis and routine testing to discover activity is not an enabled invention—it is a research plan. *Wyeth* observed that "[o]ur cases have described limits on permissible experimentation in the context of enablement. . . [I]n *ALZA* . . . [w]e concluded that one of ordinary skill 'would have been required to engage in an iterative, trial-and-error process to practice the claimed invention even with the help of the . . . specification.'" *Wyeth v. Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013). Idenix's witnesses testified that the '597 patent provides nothing more: a process of identifying effective 2' methyl up compounds via (1) synthesizing 2' methyl up compounds and (2) screening to determine which are "effective to treat HCV." JMOL at 5-8. The issue is not whether the evidence at trial was "critically deficient." Opp. at 3. The evidence provided by Idenix was explicit.

Wyeth concluded that a "lengthy" research plan, regardless of whether it is routine, is not an enabled invention. *Id.* at 1386. Here, an Idenix scientist testified that synthesizing and testing 37 compounds a month "seems like a lot." JMOL at 8. Idenix does not identify contrary testimony as to the speed of synthesis. Nor does it dispute that the synthesis/testing of just one million nucleosides (0.1% of a billion) would take 2252 years. Instead, Idenix states this "argument [was not] presented to the jury." Opp. at 10. That is incorrect. Dr. Secrist agreed with Idenix's witnesses. Tr. 1562:13-1563:1; 1709:24-1710:5 (Secrist). Arguments about enablement under *Wyeth* are legal questions; the underlying evidence was presented at trial.

Idenix also asserts that the "[t]he record here is far different" from *Wyeth*. But the inferences it requests are indistinguishable.

- Idenix requests an inference that the '597 patent discloses "several species of 2'-methyl up ribonucleosides, . . . multiple known routes for making the claimed ribonucleosides, and extensive biological data for multiple compounds." Opp. at 8. So too in *Wyeth*. The Federal Circuit

"accept[ed] as true" that, in addition to sirolomus, "[i]t was also known that there were four additional compounds with the same macrocyclic ring . . . but different substituent groups" that "have immunosuppressive and antirestenotic effects." 720 F.3d at 1383, 1385. There was also no argument that synthesis of rapamycin compounds was unpredictable, just "lengthy." *Id.* at 1386. Indeed, rapamycin compounds were known since at least 1977. Opp. Ex. 1, 3:1-10.

- Idenix argues that "a defined target (NS5B)" and required structure ("2'-methyl up") were known. Opp. at 8-9. The same was true in *Wyeth*. 720 F.3d at 1383-84 (POSA knew that sirolomus acts "by binding two proteins" and the candidate must have "the same macrocylic ring").
- Idenix also argues that in the nucleoside field it is common to work with and screen classes that encompass "billions" of compounds. Opp. at 10. This is exactly the argument made and rejected in *Wyeth*—synthesizing and screening "millions of compounds" was "routine." *Id.* at 1384-1385. Indeed, the *Wyeth* patent disclosed "assays to screen[.]" *Id.* Routine or not, a plan to screen "a lot of compounds" (Tr. 1918:11 (Meier)) is not patentable.
- Idenix claims that *Wyeth* is distinguishable because, within the broad structural limitations of the present claims, the number of compounds that are effective to treat HCV is "significantly smaller." Opp. at 9. This is the identical needle in a haystack argument presented by *Wyeth*: "the number of compounds that would exhibit the recited functional effects would be ***significantly smaller***" than the theoretical combinations claimed. 720 F.3d at 1384.

Idenix tries to avoid the needle-in-a-haystack problem by suggesting that Dr. Meier testified a POSA reading the patent would seek "a substituent at the 2'-down position that 'would mimic hydroxy in some way, shape or form'" and would be informed by "steric hindrance and electronegativity." Opp. at 4. Dr. Meier gave no such testimony. The quotations were from Dr. Storer, a fact witness. He was not speaking about a POSA reading the '597 patent in 2000. He joined Idenix ***after*** the application for the '597 patent was filed and was testifying about his own work later leading to the '600 patent.

Tr. 1155:20-1158:7; DX-235. Moreover, even if Dr. Meier had provided this testimony regarding the '597 patent, it is no different than *Wyeth*, where the POSA knew that for rapamycin compounds to be effective they "must be permeable across cell membranes" and that "permeability typically occurs below . . . 1,000 -1,200 Daltons." 720 F.3d at 1384. While this "further limit[ed] the universe" of potential compounds (*id.*), it was insufficient for enablement.

Idenix's assertion that there is only a "small class" of compounds whose activity would already be known and only needed to be "confirm[ed]" with screening (Opp. at 9) is not supported by any evidence. All Dr. Meier testified to is that the number of 2' methyl up compounds is "significantly smaller" than billions when limited to those that "should be an inhibitor of the NS5B polymerase." Opp. at 3-4; Tr. 1917:20-1918:19. He testified that the field of "modified nucleosides activity for HCV" was in its "infancy" in 2000-2001 (Tr. 1927:23-1928:5), and that HCV drug discovery was "unpredictable" even as late as 2012, when he began working in the field. Tr. 1929:8-11. Indeed, Idenix did not controvert that it repeatedly made 2' methyl up compounds that were inactive when screened. DX-338, Tr. 1448:1-1450:23 (Seeger). Far from "readily visualiz[ing] 'the other compounds'" (a term never used by Dr. Meier), he opined that "within the patent, there are screening methods described or included to test the compounds for the activity." Tr. 1855:9-14. His subsequent testimony then focused solely on whether nucleoside ***synthesis*** was routine but provided no other way to identify active compounds. Tr. 1919:20-1925:13. If Dr. Meier was aware of other methods to identify the full scope of effective 2' Methyl nucleosides besides screening, he certainly did not tell the jury.

Dr. De Francesco explicitly testified that "[w]e use the ***screening*** because ***that is a way you actually cut down the number of compounds, by removing all inactive ones*** to a few interesting ones." Tr. 1970:19-21; 1968:20-1970:25; 1979:6-1989:20. The head of the lab that synthesized Idenix nucleosides agreed: "you don't know whether or not a nucleoside will have activity against HCV until you make it and test it." Tr. 1334:6-10 (Gosselin).

Idenix miscites Dr. Secrist's testimony (Opp. at 6) that "artisans would only need to test 'a small number.'" The quoted testimony is about a Merck patent filed in ***2009***, (Tr. 1698:5-13; PX-1794A), unrelated to nucleosides, on which Dr. Secrist is an inventor, and what he actually said was that "***a lot of compounds were made***, but compared to a billion, it was a small number." Tr. 1710:16-17. He noted that the number of compounds necessary to synthesize depends on "the situation from the prior art." Tr. 1709:14-21. And like Idenix's experts, he pointed to testing to identify activity: "first you have got to make the compound, and then you have got to test[.]" Tr. 1587:13-17.

Idenix's arguments regarding acclaim in the field for the "key" "visualiz[ation]" of "2'-methyl up"[1] and corresponding use of that structural motif by other companies do not avoid *Wyeth*. Opp. at 3, 9. That Idenix may have identified a large class of candidate compounds worth making and screening does not translate to a disclosure that enables the full scope of its claims. "Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others." *Ariad Pharms. v. Eli Lilly,* 598 F.3d 1336, 1353 (Fed. Cir. 2010) (*en banc*). The application of *Wyeth* and *ALZA* is a matter of law, not a referendum on Idenix's scientific merit.

Idenix's attempts to distinguish *Wyeth* and *ALZA* on the law fare no better. The unpublished decision *Pfizer v. Teva*, involved a claim limited to a ***single*** defined chemical compound and whether the specification provided "a detailed recipe" for separating different enantiomers (three-dimensional orientations) of that one compound. 555 F. App'x 961, 966-67 (Fed. Cir. 2014). The question here is not separating different enantiomers of one compound but, rather, whether Idenix enabled the full

[1] Notably, the cited evidence (at 6-7) uniformly refers to Idenix's work as 2' methyl up, 2' OH down. PX0677.001 (Gilead making "2'CH2OH" [2' methyl up, OH down] at time of Stuyver/Schinazi exchanges); PX-0764.0023 (grant citing Idenix work as "2'-modifications (methyl[])" of natural nucleosides, not modifications at other locations); PX0702.0018 (DeFrancecso article referring to a single compound:"beta-D-2'-methyl-ribofuranosyl-guanosine (Fig. 6, compound 13)"). This confirms the problem presented by the patent—Idenix witnesses testified that only 2' methyl, 2' OH compounds are exemplified as active, leaving the work of finding other compounds to experimentation.

scope of ***all*** effective 2' methyl nucleosides as of 2000 when the field of "modified nucleosides activity for HCV" was in its "infancy," and that requires screening many compounds.[2] (Tr. 1927:23-1928:5.)

Abbott Biotech v. Centocor Ortho Biotech affirmed *ALZA:* "the need to engage in 'an iterative, trial-and-error process to practice the claimed invention,' . . . precludes a finding of enablement." 35 F. Supp. 3d 163, 178-79 (D. Mass. 2014). Idenix's quoted language (at 8), relates to a "factual dispute" that made summary judgment of enablement premature. In contrast, the record here is closed.[3]

Finally, Idenix ignores the independent non-enablement argument presented at JMOL 8-9. The claims are not limited to nucleosides that are "effective" due to inhibiting polymerase, and the patent teaches that compounds may act "by other pathways." PX-1525 at 139:30-32. The decision of Idenix's witnesses to focus solely on the HCV polymerase renders their testimony legally deficient because it does not match the claim scope.

II. Idenix's Responses to *Liebel-Flarsheim* Invalidity Are Deficient as a Matter of Law

First, Idenix relies on *Pfizer*, where the method of separating enantiomers was "already well known in the art," to argue that it was not required to enable the full scope of the claim because "[a]n explicit teaching for every species is not required." Opp. at 10-11 (citing 555 F. App'x at 967). But that is not this case. Here, Idenix's witnesses testified that they were unable to make 2' methyl up, 2' fluoro down for many years despite repeated attempts. ***Second,*** Idenix argues that the '597 patent discloses a genus, not just two species. Opp. at 11. *MagSil v. Hitachi Global Storage Techs.* (JMOL at 11) affirms the applicability of *Liebel* to opened-ended claims that encompass a number of species. 687

[2] *Falko Gunter Falkner v. Inglis* claimed a method involving deactivating "essential regions" required for the poxvirus to replicate. 448 F.3d 1357, 1365 (Fed. Cir. 2006). At the filing date the "essential regions" were known to a POSA. *Id.* at 1365. There was no need to search. Here, the '597 patent teaches that screening must occur to discover active compounds beyond those with 2' 3' OH down.

[3] *Alcon Research Ltd. v. Barr Labs., Inc.* 745 F.3d 1180, 1184 (Fed. Cir. 2014); (Opp. at 5) involved a method of using a single compound, PECO, to increase stability where enablement was found because there was "***no evidence*** that ***any experimentation*** . . . [was] necessary in order to practice the claimed invention."

F.3d 1377, 1384 (Fed. Cir. 2012). ***Third,*** Idenix's ***attorneys*** argue that there is no teaching away from 2' fluoro down in the specification. Opp. at 11. Idenix's witnesses did not so testify. To the contrary, the inventor of the '597 patent and Dr. Meier both testified that the patent expressly excludes fluoro at the 2' down position but includes it at other locations. JMOL at 10; Tr. 456:17-457:3 (Sommadossi); Tr. 1931:9-16 (Meier). Dr. Secrist testified that "[f]luorine is completely directed away from" and "specifically excluded." Tr. 1613:19-1614:11. His conclusion was not challenged. *See Integra Lifesciences I v. Merck KGaA,* 496 F.3d 1334, 1345 (Fed. Cir. 2007) (on JMOL "the court should give credence to . . . 'evidence supporting the moving party that is uncontradicted and unimpeached'").

Idenix identifies persons other than the inventors who made 2' methyl up, 2' fluoro down years after the priority date. Opp. at 11-12. This is a *non-sequitur*. *Liebel-Flarsheim Co. v. Medrad* focused on repeated failure of the inventors to make jacketless apparatus using techniques in the specification. 481 F.3d 1371, 1380 (Fed. Cir. 2007). That the ***accused infringer*** in *Liebel* made the apparatus was legally irrelevant. The same holds for Mr. Clark, inventor of Gilead's patent on 2' methyl up, 2' fluoro down nucleosides.[4] Even if, for purposes of this motion, the Court credits Dr. Griffon, the synthesis Idenix cites allegedly occurred in 2003 and 2005, after years of repeated failure despite involving experts, and only after he developed what he alleged was his own synthesis. Tr. 1180:1-1183:17.

Idenix's patent is only enabled for claims limited to compounds having 2', 3' OH down. Given the admitted "infancy" of the field of nucleosides effective for HCV, the '597 patent specification's failure to disclose synthesis or select data for nucleosides other than 2', 3' OH down defeats enablement. JMOL at 11 n.5; 50(a) at 6. *See ALZA Corp. v. Andrx Pharms. LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010)) (reliance on general understanding of a POSA "[cannot] substitute for a basic

[4] Idenix's suggestion that the '597 patent "guided" Mr. Clark (Opp. at 12) stretches the record beyond recognition. Idenix's experts acknowledged that there is no discussion of fluoro down in the '597 patent, much less a guide to synthesis of such compounds. Tr. 1931:9-16 (Meier).

enabling disclosure"). But ***regardless of this broader defect***, the '597 patent's exclusion of fluoro at 2' down, coupled with repeated failures to make 2' methyl up, 2' fluoro down compounds with the help of experts is fatal under *Liebel*.

III. The Patent Violates the "Four Corners" Rule and Separately Only Possesses 2' OH

Idenix recognizes that when "claim limitations were wholly missing from the specification" the claims are invalid for no written description. Opp. at 16. The claim limitation reciting effective 2' methyl compounds ***with anything but H at 2' down*** is wholly missing from the specification.[5]

Idenix asserts that the "effective to treat HCV" limitation ensures the claims are very narrow because only "a small number" of compounds covered by the structural limitations will be effective. Opp. at 16. In *ICU*, there were only ***two*** species of valves, spiked and spikeless. *ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1378 (Fed. Cir. 2009). The claim was generic to both. *Id.* It was nonetheless invalid because there was only disclosure in the four corners of the specification of spiked valves, despite testimony that a POSA would understand from the "figures and descriptions" generally that the specification is "neutral" as to spikes. *Id.* at 1378-79. In the '597 patent there is only a disclosure of "narrower" defined lists of particular substituents at 2' down, and therefore by logical necessity only a disclosure of effective compounds with substituents selected from these lists. The broader, open-ended limitation of "anything but H" exceeds the four-corners of the disclosure.

Idenix asserts that there is no need to identify the portions of the specification that disclose all effective 2' methyl up molecules with "anything but H" because Dr. Meier testified that the "'key' invention[s] . . . 'are 2'-methyl up, and [that structure] should be an inhibitor of the NS5B[.]'" Opp. at 13, 16. Even fully crediting this testimony, the patent is invalid. Dr. Meier simply tries to convert the written description inquiry into an obviousness inquiry, which the law forbids. *ICU*, 558 F.3d at 1377.

[5] "The scope of [Idenix's] right to exclude cannot 'overreach the scope of [its] contribution to the field of the art as described in the patent.'" *Centocor v. Abbott Labs.*, 636 F.3d 1341, 1353 (Fed. Cir. 2011).

There is no waiver. Dr. Secrist testified that, in contrast to the claims (Tr. 1577:4-25), when he reviewed the '597 patent, he found no disclosure that the invention was a method for treating HCV with a nucleoside that has 2' methyl up and "***anything but H down***." Tr. 1606:13-25. He testified that the patent states that its invention is limited to "Formulas I through XVIII," Tr. 1607:23-1608:3, and that only 2 of those require 2' methyl up. Tr. 1608:13-16. He noted that the 2' down position in each of those formulas is "OR3," and that although that definition lists a "large number" of substituents, "it is dramatically narrower than the Court's construction of Claim 1" and shows no "possession of, of the breadth of Claim 1[.]" Tr. 1608:7-1609:8. For the five formulae that permit methyl up at 2' amongst many possibilities, Dr. Secrist explained that the formulae's list of substituents explicitly exclude fluoro down and therefore are once again narrower than the claims. Tr. 1598:13-1599:7, 1614:1-16. Dr. Meir also testified to the use of definitions for 2' down substituents. JMOL at 11. The Rule 50(a) motion asserted the same (at 2-3): "the 'Summary of the Invention' limits the invention to nucleosides within 18 Formulas, none of which correspond to the claimed subgenus" of "nucleosides with a 2' methyl up and ***anything but hydrogen at 2'***[.]" Whether the Court uses "broader/narrower," or "open/closed," is immaterial.

Finally, the JMOL (at 17) separately seeks a ruling of invalidity because the patent only shows possession of 2' methyl up, 2', 3' OH down at best. Tr. 1609:19-1613:25 (Secrist); Rule 50(a) at 4. *Chiron v. Genentech, Inc.,* 363 F.3d 1247, 1255 (Fed. Cir. 2004). Idenix ignores this argument.[6]

IV. Mr. Carter Failed to Apportion the Royalty Base to Account for Gilead's Contributions

Mr. Carter testified that demand for sofosbuvir is impacted by contributions separate from the '597 patent, including 2' fluoro down and sofosbuvir's prodrug. JMOL at 21-22. He also testified

[6] By incorporating its Rule 50(a) arguments into its Rule 50(b) motions, Gilead did precisely what was required by Rule 50(b): renew its JMOL motions following entry of judgment. Idenix's citation (at 25) to *Masimo* is inapt. The Federal Rules do not require the movant to "repeat[ ] the details of the original [JMOL motion] over and over again." *Kline v. City of Kansas City, Fire Dep't*, 175 F.3d 660, 670 (8th Cir. 1999); *see also Fort James Corp. v. Solo Cup Corp.*, 412 F.3d 1340, 1347 (Fed. Cir. 2005).

that those are Gilead's contributions, not Idenix's, stating that "Idenix would be bringing its patent to the table, and Gilead would be bringing everything else. Gilead has to provide the drug that cures you, the prodrug that gets the curative drug in the body." Tr. 746:14-17. Similarly, Idenix's counsel told the jury that Gilead "made [Idenix's invention] better" by "ma[king] certain improvements, such as adding something called fluorine down and adding something called prodrug." Tr. 238:10-18. In light of that testimony, Mr. Carter's failure to apportion the royalty base to include only revenue attributable to the '597 patent, combined with his repeated references to Gilead's large revenues, violated EMVR. Additionally, *AstraZeneca* shows that, regardless of EMVR, Mr. Carter was still required to apportion the base—a defect noted by Gilead (JMOL at 24) but never addressed by Idenix.[7]

Idenix cites *AstraZeneca AB v. Apotex Corp.* (at 23) to argue, incorrectly, that because this is a pharmaceutical case, EMVR is inapplicable and apportionment is unnecessary. Idenix asks this Court to adopt the very rule *AstraZeneca* rejected: "we do not hold that the [EMVR] is *per se* inapplicable in the pharmaceutical context." 782 F.3d 1324, 1337-38 (Fed. Cir. 2015). Additionally, the specific facts that led the court to find EMVR inapplicable in *AstraZeneca* are absent here. *See* JMOL at 23.

Moreover, under *AstraZeneca*, apportionment of the base is required regardless of EMVR. *AstraZeneca* states that, even "while [EMVR] does not apply," "the damages determination nonetheless requires a ***related inquiry***." 782 F.3d at 1338. That "related inquiry" addresses situations where "a patent covers the infringing product as a whole" but the claims combine "unconventional elements" (described as "the patentee's invention") with other elements that were not invented by the patentee. *Id.* In those situations, it is necessary to "determine how to account for the relative value of the patentee's invention in comparison to the value of the [other elements]." *Id.* Only after conducting

[7] Gilead does not "ignore" that Mr. Carter "applied a reduction to remove Harvoni's other compound, ledipasvir." Opp. at 23 n.10. Gilead specifically cited that reduction as grounds for JMOL, because Mr. Carter never explained the basis of it to the jury. JMOL at n.13. More fundamentally, that reduction does not account for the portions of sofosbuvir that have nothing to do with the '597 patent.

that analysis and concluding that the inventive element in *AstraZeneca* was "substantially responsible for the value," did the court approve of using the entire value of the product as the base. *Id.* at 1339.

Idenix asserts that its patent covers its allegedly inventive element (2' methyl up) and other elements contributed by Gilead (2' fluoro down and the prodrug). Tr. 746:13-19. Unlike *AstraZeneca*, those other elements contribute to sofosbuvir's value. Thus, Mr. Carter was required to apportion his base to account for the relative value of 2' methyl up in comparison to 2' fluoro down and the prodrug.

Idenix is wrong to suggest (at 24) that it can include the value of the prodrug in the base merely because "the claims cover methods that include delivery by prodrug." Even if Idenix's claims cover sofosbuvir as a whole, *AstraZeneca*'s "related inquiry" applies "[w]hen a patent covers the infringing product as a whole," and it requires separating the value of elements Idenix contributed from those it did not. 782 F.3d at 1338. Similarly, *Lucent* and its progeny hold that simply drafting claims to cover an end product does not satisfy the EMVR when the patentee invented only a feature of that product. *See* JMOL at 23; *GPNE Corp. v. Apple, Inc.*, 2014 WL 1494247, at *12-13 (N.D. Cal. Apr. 16, 2014) (claiming "the entire device" does not avoid EMVR, as patentees would "simply draft[] patent claims to cover end products"). Idenix's assertion (at 23) that Gilead has not explained how sofosbuvir is "capable of being divided" is misguided because Mr. Carter testified to the division—(1) 2' methyl up; (2) 2' fluoro down; and (3) the prodrug (Tr. 746:14-17)—and apportionment was Idenix's burden.

CSIRO does not provide a "licenses" exception to EMVR or apportionment, holding only that it was unnecessary to apportion the base to the smallest-salable unit when the damages methodology did not use a base, but instead used a per-unit royalty. (JMOL at 22.) Unlike *CSIRO*, Mr. Carter ***did*** use a base, and numerous cases (including seminal cases such as *Lucent* and *VirnetX* (JMOL at 21)) have required satisfaction of EMVR or apportionment notwithstanding comparable licenses.

V. Mr. Carter Failed to Perform the Required License Comparability Analysis

Idenix mischaracterizes Gilead's argument by relying on cases holding that a license may be

admissible despite lacking "identity of circumstances" to the hypothetical license. Opp. at 20-21. But, Gilead does ***not*** challenge ***admissibility***. Rather, Gilead challenges Mr. Carter's failure to meet the foundational requirements for relying on unaltered rates in those licenses, because he did not "account for differences in the technologies and economic circumstances" so as to "permit[] the jury to properly discount the [] license[s]." *Finjan, Inc. v. Secure Computing*, 626 F.3d 1197, 1211-12 (Fed. Cir. 2010).

Portfolio Licenses: Mr. Carter failed to account for the difference between portfolio licenses and single patent licenses. Idenix argues (at 21) that *Lucent* is distinguishable because only one specifically identified U.S. patent in the Merck-Roche license had issued at the time of that license. But the Merck-Roche license included a covenant not to sue on *every* Merck patent, not just specifically identified ones. PX-1606.0004. Additionally, *Inventio AG v. Thyssenkrupp Elevator*, 2014 WL 554853 (D. Del. Feb. 6, 2014) (relied on by Idenix) supports Gilead. That court allowed use of an "umbrella" license only after the expert "took [] into account" that "a significant downward adjustment to th[e] royalty rate would be warranted," and did not "simply extract a [] rate from [that] license." *Id.* at *4.

Mr. Carter also did not testify that in "the industry" the "number of patents would not change the analysis." Opp. at 21. Rather, Mr. Carter testified that, for the portfolio licenses "in this case," the rate did not change as new patents within the portfolio issued or expired. Tr. 790:18-791:6. Moreover, Mr. Carter cannot simply disregard *Lucent*, nor tell the jury to: "[n]o reasonable juror could consider these broad portfolio license agreements to be comparable in scope to a license for only [the '597] patent." *AVM Techs., LLC v. Intel Corp.*, 2013 WL 126233, at *3 (D. Del. Jan. 4, 2013).

Risk: Mr. Carter failed to account for differences in risk and never "testified that the risks were comparable." Opp. at 22. To the contrary, he testified that at the Merck-Roche negotiation, there was "no guarantee" that Roche's drug would obtain FDA approval or ever be sold (as it never was), whereas at the hypothetical negotiation, Gilead had "*already* obtained FDA approval," and the parties "knew that Gilead would begin selling Sovaldi imminent[ly]." Tr. 785:4-787:21. Mr. Carter disregarded

that difference in risk as "neither here nor there," because Roche was ***expected*** to do what Gilead ***actually*** did. Tr. 786:23-787:2. By equating expectations with certainty, Mr. Carter failed to account for a key difference. The Federal Circuit rejected similar use of a license, explaining that if "the level of risk . . . [at the hypothetical negotiation] differed from the risk quantified in the [relied-upon license] then the [relied-upon license] does little to set the value of the [hypothetically licensed technology] at a comparable figure." *Integra Lifesciences I v. Merck KGaA*, 331 F.3d 860, 870-871 (Fed. Cir. 2003).

Technical Comparability: Idenix's assertion (at 21-22) that it was sufficient for Mr. Carter to testify that the patents covered by the Merck-Roche license "concerned a patent directed to HCV treatment" contradicts the Federal Circuit precedent cited in Gilead's JMOL (at 19 n.11), and unaddressed by Idenix.[8] Idenix's separate assertion of technical comparability because the invention in the patents covered by the Merck-Roche license is "the same as Idenix's invention," is pure attorney argument. Other than the vague and insufficient reference to "HCV treatment," no witness ever told the jury which patents were included in the Merck-Roche license or what they covered.

Non-Patent Assets: Idenix wrongly asserts that it was sufficient that the jury heard that the non-patent assets in the Pharmasset-Roche agreement related to the patented HCV technology. That assertion ignores the fundamental problem with Mr. Carter's analysis—that he failed to make any adjustment to account for the value of those non-patent assets, including the value of PSI-6130 itself.

VI. This Court Should Sever and Stay the Ongoing Royalty Analysis

Significant fact issues remain relating to ongoing royalties (D.I. 555 at 13) and, thus, the most efficient use of judicial resources is to sever and stay. The cases cited by Idenix do not include requests to sever or stay, and this Court has previously postponed the ongoing royalty determination until after appeal. *See Comcast IP Holdings I v. Sprint Comm's*, 2015 WL 4730899, at *10 (D. Del. Aug. 10, 2015).

[8] Dr. Putnam's reliance on the Gilead-Chiron license is not inconsistent. Opp. at 22 n.9. That license names sofosbuvir as a licensed product. DX-2365.0005. The Merck-Roche license does not.

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